REMARKS

The outstanding Office Action addresses and rejects claims 1-37.

In the Drawings

The Examiner objects to the drawings for failing to show the "detents" recited in claim 12. Claim 12 has been amended to remove the term "detents," thereby obviating the basis for this objection. Amended claim 12 now recites first and second *members, each member extending through an opening formed in the body*. Support for this amendment can be found throughout the specification and in the drawings, for example, at page 10, line 18 to page 11, line 4. No new matter has been added.

The Examiner further objects to the drawings for using reference character "82b" to designate different openings. Applicants have amended Figure 3 to correct this typographical error. Specifically, one of the characters "82b" is replaced with character "82a." Applicants submit a Replacement Drawing showing changes made, and a clean version of the Replacement Drawing.

The Examiner further objects to the drawings for failing to comply with 37 C.F.R. 1.84(p)(5) because they do not include "body 13." Applicants respectfully disagree. Figure 1 clearly indicates body 13 mating the tissue grasping element 14 and the actuating member 16. In this embodiment, the body 13, as described on page 8 of the specification, is in the form of a rivet or screw that forms a pivot point between elements 14 and 16. Accordingly, Applicants respectfully request reconsideration and withdrawal of this objection.

In the Specification

The Examiner objects to the specification for using the same reference numeral to refer to different parts shown in the drawings. Applicants have amended the specification to correct any typographical errors which may have resulted in duplicate reference numerals. No new matter

has been added. Applicants thank the Examiner for taking the time to carefully review the specification.

The specification is further objected to as failing to provide proper antecedent basis for the claimed "detents" recited in claim 12. As previously stated, claim 12 has been amended to remove the term "detents," thereby obviating the basis for this objection.

35 U.S.C. §112, Second Paragraph

Claim 23 is rejected pursuant to 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the Examiner argues that it is unclear how the tissue grasping element can be fully disposed within the inner lumen of the body in the open position. The Examiner refers to Figure 3, which illustrates the tissue grasping element in a closed position.

Applicants refer the Examiner to Figures 7A, 7B, and 8, which illustrate embodiments of a medical instrument having a tissue grasping element fully disposed within the inner lumen of the body, as recited in claim 23. Accordingly, Applicants respectfully request reconsideration and withdrawal of this rejection.

35 U.S.C. §103(a)

Independent Claims 1 and 37

Claims 1-15 and 37 are rejected pursuant to 35 U.S.C. §103(a) as being obvious over U.S. Patent No. 5,893,878 of Pierce in view of U.S. Patent No. 5,954,057 of Li.

Independent claim 1 is directed to a medical instrument effective to assist in positioning an internal organ during a surgical procedure. The medical instrument includes a body, a tissue grasping element appended to the body and having at least one *tissue penetrating* claw selectively movable between an open position and a closed position, and an actuating member mated to the body and effective to move the tissue grasping element between the open and closed

positions. The device further includes a flexible member having a portion secured to the body and at least one free end that is selectively fastenable to a support. Independent claim 37 is directed to a method for positioning a body organ using essentially the same medical instrument recited in claim 1.

The Examiner argues that Pierce discloses the medical instrument recited in claims 1 and 37, but admits that Pierce does not disclose a flexible member having a portion secured to the body with one free end that is fastenable to a support. Thus, the Examiner relies on Li to teach a flexible member attached to a tissue penetrating structure, arguing that it would have been obvious to modify Pierce to include a flexible member as taught by Li. Applicants respectfully disagree.

At the outset, the Examiner has improperly interpreted Pierce to disclose a device having at least one *tissue penetrating claw*, as required by claims 1 and 37 of the present invention. Pierce does not teach or even suggest the use of a *tissue penetrating claw*. As shown in Figure 1 of Pierce, the device includes jaw members 26 and 28 having tissue *contacting* surfaces which are designed to *grip* tissue between the contact surfaces. These jaw members cannot be considered "claws," as taught by the present invention. A claw does not grip tissue, but rather has a "semi-circular shape" and includes a "tissue piercing end." (Specification, pp. 8, lines 15-17.) In use, a claw is effective to penetrate into and grasp or hook-onto tissue. The jaw members taught by Pierce are not, and do not function as, "tissue penetrating claws." Accordingly, Pierce fails to teach or suggest a device having any type of tissue penetrating claw, and therefore the combination of Pierce and Li cannot teach the present invention.

Applicants further note that there is no motivation to modify Pierce, in view of Li, to include any type of tissue penetrating claw because Pierce explicitly teaches away from the use of a traumatic penetrating member. In the "Background of the Invention" section, Pierce distinguishes penetrating devices, referring to them as "traumatic" surgical graspers. Pierce designs around such devices by providing a device that "enable[s] the retention and manipulation of the tissue without effecting [sic] the structural integrity of the structure associated with the

tissue." (Col. 2, lines 53-55.) Accordingly, a person having ordinary skill in the art would not modify Pierce to include a tissue penetrating claw.

Even if Pierce could be interpreted to disclose a device having a tissue penetrating claw, there are several reasons why Pierce cannot be modified to include a flexible member as taught by Li. First, Pierce is a totally different type of tool than the device disclosed by Li. Pierce is a rigid, elongate scissor-type device having a trigger mechanism used to actuate opposed grasping members. Li, on the other hand, is a small suspension clip having a suspension strap attached thereto. A person having ordinary skill in the art would not combine isolated features of these two, very distinct references. Second, there is no motivation to modify Pierce to include a flexible member for manipulating the device. This would provide only redundancy since Pierce already includes a handle member attached near the proximal end of the device for actuating the tissue contacting members and manipulating the tissue.

Even if a flexible member were attached to the device disclosed by Pierce, it would be so awkward to operate, that its inclusion would be meaningless. The rigid, elongate shape of the device would make it very difficult to hold and manipulate using a flexible elongate member. Patient injury could result. Moreover, the flexible member would be meaningless since it cannot be used to hold and manipulate the tissue. The Pierce device lacks any type of locking mechanism to lock the levers 48 and 50 in one of the open or closed positions, thus tissue can only be grasped and manipulated by holding the levers in the closed position. In sum, there is no suggestion or motivation to modify Pierce to include any type of flexible member, much less the flexible member taught by Li, and the use of such a flexible member would be meaningless.

Accordingly, for all of the aforementioned reasons, claims 1 and 37 are patentably distinct from Pierce and Li, taken alone or combined. Claims 2-31 are allowable at least because they depend, either directly or indirectly, from allowable claim 1.

Independent Claim 32

Independent claim 32 is rejected pursuant to 35 U.S.C. §103(a) as being obvious over U.S. Patent No. 5,893,878 of Pierce.

Claim 32 is directed to a medical instrument effective to assist in positioning an internal organ during a surgical procedure. The instrument includes a body, a tissue grasping element operatively disposed within the body and having at least one tissue penetrating claw selectively movable between a retracted position and an extended, tissue grasping position, and a flexible member having a first end secured to the body and a second end. The device also includes a handle mated to the second end of the flexible member, and an actuating member slidably communicating between a portion of the handle and the tissue grasping element and effective to move the tissue grasping element between the retracted and extended positions. A lever is movably disposed on the handle and attached to the actuating member. The lever is effective to move the actuating member and thereby move the tissue grasping element.

The Examiner argues that Pierce discloses a body 10, two tissue grasping claws 26 and 28, a shaft or member 12, a handle 20 mated to the second end of the member 12, and an actuating member 32 slidably communicating between the handle and the tissue grasping claws 26 and 28 and effective to move the claws 26 and 28 between the retracted and extended positions. The Examiner further argues that Pierce discloses a lever 48, 50 movably disposed in handle 20 and attached to the actuating member 32 to move the actuating member 32, and thereby move the tissue grasping claws 26 and 28. The Examiner admits that Pierce fails to teach a flexible member, but argues that it would have been obvious to have made member 12 flexible. Applicants respectfully disagree.

The Examiner has relied on the same component in the device taught by Pierce to teach two separate elements recited in claim 32. Specifically, the Examiner refers to the instrument itself as the *body 10*, but then relies on the parts forming the body or device 10 to teach other claimed components. The only part of device 10 of Pierce that can be considered a body, according to claim 32, is the shaft 12, since claim 32 requires that a tissue grasping element be

operatively disposed *within* the body, and the shaft 12 is the only portion of the Pierce device that has something operatively disposed therein. The Examiner has, however, argued that it would have been obvious to make the shaft 12 flexible, thereby relying on the shaft 12 to teach both the body and the flexible member recited in claim 32. The shaft 12 cannot be both the body and the flexible member, as these are separate components recited in claim 32. In fact, claim 32 requires that the flexible elongate member have a first end that is secured to the body. Accordingly, Pierce is deficient with respect to at least one of the components recited in claim 32. As a result, the Examiner's argument that it would have been obvious to modify shaft 12 to be flexible is flawed, as such a modification would still result in a deficiency with respect to at least one of the claimed components.

Not only does Pierce fail to teach or even suggest a flexible member, but a person having ordinary skill in the art would not be motivated to modify Pierce to include any type of flexible member. Claim 32 requires the flexible member to have a first end secured to the body, and a second end mated to the handle. The addition of such a flexible member to Pierce would be completely useless and would not serve any function, as the flexible member would merely extend between the handle 20 and the shaft 12, which are already attached to one another. The flexible member recited in claim 32 is effective to connect the handle to the body. The use of a flexible connection between the handle and the body, rather than a rigid connection as taught by Pierce, is advantageous in that the handle can be placed at any location outside of the human body (e.g., draped over the retractor) to maintain the position of the body organ being grasped. The device disclosed by Pierce would have to be modified significantly to include such a feature.

Applicants further note that claim 32 requires a tissue grasping element having at least one *tissue penetrating claw*. As previously stated, Pierce does not include, and specifically teaches against the use of, a *tissue penetrating claw*.

Accordingly, claim 32 distinguishes over Pierce, and therefore represents allowable subject matter. Claims 33-36 are allowable at least because they depend, either directly or indirectly, from allowable base claim 32.

Conclusion

In view of the amendments and remarks above, Applicants submit that claims 1-37 are in condition for allowance. Applicants encourage the Examiner to telephone the undersigned in the event that such communication might expedite prosecution of this matter.

Respectfully submitted,

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Lisa J. Michaud
Reg. No. 44,238
Attorney for Applicants

NUTTER, McCLENNEN & FISH, LLP
World Trade Center West
155 Seaport Boulevard
Boston, MA 02110-2604
Tel: (617)439-2550
Fax: (617)310-9550

AMENDED CLAIMS WITH MARKINGS TO SHOW CHANGES MADE

12. (Amended) The medical instrument of claim 11, wherein the actuating member comprises first and second opposed [detents]members, each member extending through an opening formed in the body.

REPLACEMENT PARAGRAPH AT PAGE 8, LINE 1
WITH MARKINGS TO SHOW CHANGES MADE

FIG. 1 illustrates one embodiment of a medical instrument 10 according to the present invention. In general, the medical instrument includes a body 13, a tissue grasping element 14, and an actuating member 16. The body 13 mates the tissue grasping element 14 with the actuating member 16, and can have any shape and can be any type of connector, or similar device. In one embodiment, the body 13 is a rivet or screw which forms a pivot point between the tissue grasping element 14 and the actuating member 16. Alternatively, the body 13 can be a separate element disposed around pivot point [13] to join the tissue grasping element 14 and the actuating member 16, or it can be formed integrally with the tissue grasping element 14 and the actuating member 16.

REPLACEMENT PARAGRAPH AT PAGE 9, LINE 25
WITH MARKINGS TO SHOW CHANGES MADE

Once the tissue is firmly grasped by the medical instrument 10, the flexible member 18 can be used to retract and position the body organ. The flexible member 18 includes a proximal, free end 19 that is selectively fastenable to a support (not shown), and a distal end mated to the body 13, or any other part of the medical instrument 10. A rivet, screw, snap, buckle, adhesive, or similar attachment member can be used to secure the flexible member 18 to the body 13. Similarly, the free end 19 of the flexible member 18 can include a snap, buckle, hook and eye closure, or similar device for tying or securing the flexible member 18 to a support. The length of the flexible member 18 should be sufficient enough to allow the flexible member 18 to extend from the body organ to the support or some other position outside the body. In use, tension is applied to the flexible member 18 to retract and position the body organ (or tissue). The free end 19 of the flexible member 18 can then be secured to a support (not shown) to maintain the organ (or tissue) in a desired position.

REPLACEMENT PARAGRAPH AT PAGE 10, LINE 18
WITH MARKINGS TO SHOW CHANGES MADE

The housing 12 of medical instrument 20 is generally elongate and includes a first surface 53, a second surface (not shown) opposed to the first surface, and side surface[s] 55 connecting the first and second surfaces. The first, second, and side surfaces 53, 55 define a cavity for receiving medical instrument 10. The side surface 55 includes two opposed proximal openings 81a, 81b from which the actuating members 16a, 16b of medical instrument 10 extend, and two opposed distal openings 82a, 82b from which the tissue penetrating claws 14a, 14b of medical instrument 10 extend. The proximal openings 81a, 81b should have a size substantially the same as the length of the actuating members 16a, 16b so as to allow a portion of the actuating members 16a, 16b to extend therefrom. The distal openings 82a, 82b, on the other hand, should be of a sufficient size to allow the tissue penetrating claws 14a, 14b to move between the open and closed positions, respectively. Preferably, the distal openings each have a length of between about 3 to 8 mm. The size of the housing or body 12 should be sufficient to hold the medical instrument 10 therein, and should have a width less than the width of the actuating members 16a, 16b to allow the actuating members 16a, 16b to protrude there from.

REPLACEMENT PARAGRAPH AT PAGE 11, LINE 10
WITH MARKINGS TO SHOW CHANGES MADE

Medical instrument 10 can be mated to, or merely disposed within, the housing or body 12. For example, the actuating members 16a, 16b and the tissue grasping element 14 can be molded into the housing 12, or they can be pivotably attached to the housing 12 with a securing device, such as with the body 13, which may be in the form of a rivet or screw as described above with respect to FIG. 1. Thus, the body 13 can extend through the first surface 53 of the housing [53]12, the tissue grasping element 14 and actuating member 16, and the second surface of the housing 12. A rivet, screw, rod, or similar attachment device can be used secure the actuating members 16a, 16b and the tissue grasping element 14 to the housing 12.

REPLACEMENT PARAGRAPH AT PAGE 11 LINE 19
WITH MARKINGS TO SHOW CHANGES MADE

The flexible member 18' is similar in placement and operation to that described with respect to FIG. 1, however, the distal end (not shown) of flexible member 18' can be mated to the housing 12, rather than the body 13. The proximal end 19' of the flexible member 18', as well as the proximal end 28 of the applicator sleeve 22, can have a shape and size adapted to provide an improved gripping surface, and to allow the medical instrument [30]20 to be secured to a support (not shown). In use, the flexible member 18' is disposed within the applicator sleeve 22 to allow the applicator sleeve 22 to slidably move with respect to the housing 12.

REPLACEMENT PARAGRAPH AT PAGE 11, LINE 27
WITH MARKINGS TO SHOW CHANGES MADE

The applicator sleeve 22 has a substantially rigid elongate body and it is effective to depress the actuating members 16a, 16b, and thereby move the tissue grasping element 14 to the open position. The applicator sleeve 22 includes an inner cavity which can be dimensioned to fit slidably over the housing 12 and the flexible member 18'. The sides of the applicator sleeve 22 should conform to the sides of the housing 12, such that movement of the applicator sleeve 22 over the housing 12 will depress the actuating members 16a, 16b. The proximal end 28 of the applicator sleeve 22 can include one or more openings 24a, 24b to enable a portion of the flexible member 18' to be grasped with respect to the sleeve 22, thereby preventing movement of the applicator sleeve 22. The length and width of the applicator sleeve 22 can vary depending on the size of the housing 12. In one embodiment, the applicator sleeve preferably has a length of 15 cm and a width of 15 mm.

REPLACEMENT PARAGRAPH AT PAGE 12, LINE 20
WITH MARKINGS TO SHOW CHANGES MADE

In one embodiment, the flexible member 18' is pulled through the inner lumen of the applicator sleeve 22 and held with tension to secure the applicator sleeve 22 onto the housing [13]12. The applicator sleeve 22 is then used to manipulate the body 12 and cause the tissue grasping element [40]14 to grasp or penetrate tissue 60. The flexible member 18' can then be released and the applicator sleeve 22 slid off of the body 12. Tension can then be applied to flexible member 18' to retract and position the body organ (or tissue). The free end 19' of the flexible member 18' can then be secured to a support (not shown) to maintain the organ (or tissue) in a desired position.

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Replacement Figure

Figure 3